

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Neil P. DESAI et al.

Serial No.: 10/731,224

Filing Date: December 9, 2003

For: COMPOSITIONS AND METHODS OF
DELIVERY OF PHARMACOLOGICAL
AGENTS

Examiner: M. Tsay

Group Art Unit: 1656

Confirmation: 4904

**SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & § 1.98**

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign patent and non-patent literature (documents numbered 18 through 47) are submitted herewith. Copies of unpublished U.S. Patent Applications (documents numbered 48 through 55) are not included herewith. This protocol conforms with the waiver of the requirement for submitting cited pending U.S. Patent Applications under 37 C.F.R. § 1.98. The Examiner is requested to make these documents of record in the application.

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of __ is enclosed.
 - ☒ A fee is required. ~~Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.~~
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of __ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling;
or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 638772000300.

Dated: July 7 , 2009

Respectfully submitted,

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